

Appln. No.: 09/373,230  
Amdt. dated: May 19, 2008  
Reply to Office Action of February 21, 2008

**REMARKS**

The Office Action has been carefully reviewed. No claim is allowed. Claims 18, 19 and 24-27 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 18-21 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While applicants disagree with this rejection and do not concede that there is new matter, this rejection is obviated by the cancellation of claim 20 and the amendment to claim 18 without prejudice.

The new claims are not subject to this rejection. New claim 26 is supported by the following disclosure at page 9 of the specification (as amended December 19, 2001):

The protein according to the present invention includes protein in general .... Variants ... can be obtained by replacing one or more amino acids in SEQ ID NO:2 ... variants, which are defective in or additionally contain one or more amino acids near to the N-terminal in SEQ ID NO:2 while retaining biological properties in the protein ... The present protein includes such

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variants as long as they induce the IFN- $\gamma$   
production by immunocompetent cells.

The language "one or more" must comprise "one or two" as the term "more" used in new claim 26 here is equivalent to "at least two". Therefore, there is support for the recitation of "one or two" amino acids replaced with other amino acids in claim 26. Support for new claims 24 and 25 are found in the paragraph bridging pages 14 and 15 of the present specification.

Withdrawal of the rejection is respectfully requested.

Claims 18-23 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the cancellation of claim 22 and the amendment of claim 18 without prejudice. The new claims are not believed to be subject to this rejection.

Withdrawal of the rejection is therefore respectfully requested.

Claims 18-23 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants believe that this rejection is obviated by the amendments to the claims. New claim 26 recites "one or two" amino acid substitutions. As SEQ ID NO:2 is 157 amino acid residues in length, a variant with only one or two amino acid substitutions in SEQ ID NO:2 would have more than 98% sequence identity with SEQ ID NO:2. Since the variant retains IFN- $\gamma$  production inducing ability, which is readily assayed as taught in the specification, and has at least 98% sequence identity to SEQ ID NO:1, this situation is analogous to "Example 14: Product by Function" of the USPTO's Synopsis of Application of Written Description Guidelines. In that example, a claim reciting for variants of the protein of SEQ ID NO:3 which are at least 95% identical to SEQ ID NO:3 and catalyzes a particular reaction was analyzed and determined to meet the written description requirements based on disclosure of only the single species of SEQ ID NO:3.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their

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allowance. Favorable consideration and early allowance are  
earnestly urged.

Respectfully submitted,

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